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**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

TAKEDA PHARMACEUTICALS  
AMERICA, INC., TAKEDA  
PHARMACEUTICALS U.S.A., INC., and  
ARIAD PHARMACEUTICALS, INC.,

Plaintiffs,

v.

APOTEX INC.,

Defendant.

C.A. No. 2:21-cv-12998-KM-AME

**ANSWER AND SEPARATE DEFENSES OF  
DEFENDANT APOTEX INC.**

Defendant Apotex Inc. (“Apotex”), by and through its undersigned counsel, responds to the First Amended Complaint filed by Plaintiff Takeda Pharmaceuticals America, Inc. (“TPA”), Takeda Pharmaceuticals U.S.A., Inc. (“TPUSA”), and ARIAD Pharmaceuticals, Inc. (“Ariad”) (collectively, “Takeda”) (ECF No. 34) as follows:

**RESPONSES AS TO THE NATURE OF THE ACTION<sup>1</sup>**

1. Apotex admits that the Complaint purports to bring an action for patent infringement under the patent laws of the United States, 35 U.S.C. § 100, *et seq.*, and admits that it submitted Abbreviated New Drug Application (“ANDA”) No. 215893 to the United States Food and Drug Administration (“FDA”), but denies any remaining allegations of this paragraph. Apotex avers that it filed ANDA No. 215893 with the FDA, seeking approval to commercially market a pharmaceutical composition comprising 15 mg and 45 mg ponatinib hydrochloride.

**RESPONSES AS TO THE PARTIES**

2. Apotex lacks knowledge and information to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

3. Apotex lacks knowledge and information to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

4. Apotex lacks knowledge and information to form a belief as to the truths of the allegations of this paragraph, and therefore denies them.

5. Apotex admits the allegations of this paragraph.

**RESPONSES AS TO THE PATENTS-IN-SUIT**

6. Apotex admits that U.S. Patent No. 9,493,470 (the “’470 patent”), issued on November 15, 2016, is entitled “Crystalline forms of 3-(imidazo[1,2-B] pyridazin-3-ylethynyl)-4-methyl-N-{4-[(4-methylpiperazin-1-yl) methyl]-3-(trifluoromethyl)phenyl} benzamide and its mono hydrochloride salt,” with Christopher K. Murray, Leonard W. Rozamus, John J. Chaber, and Pradeep Sharma as the listed inventors on the face of the ’470 patent. Apotex also admits

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<sup>1</sup> Apotex denies any allegation that may be implied or inferred from the headings of Takeda’s Complaint.

that, according to the U.S. Patent and Trademark Office's ("USPTO") electronic records, Ariad is the assignee of the '470 patent. Apotex further admits that what appears to be an uncertified copy of the '470 patent was attached to Takeda's Complaint as Exhibit A. Apotex denies the remaining allegations of this paragraph.

7. Apotex admits that U.S. Patent No. 11,192,897 (the "'897 patent"), issued on December 7, 2021, is entitled "Crystalline forms of 3-(imidazo[1,2-B] pyridazin-3-ylethynyl)-4-methyl-N-{4-[(4-methylpiperazin-1-yl) methyl]-3-(trifluoromethyl)phenyl} benzamide and its mono hydrochloride salt," with Christopher K. Murray, Leonard W. Rozamus, John J. Chaber, and Pradeep Sharma as the listed inventors on the face of the '897 patent. Apotex also admits that Ariad is listed as the assignee on the face of the '897 patent. Apotex further admits that what appears to be an uncertified copy of the '897 patent was attached to Takeda's Complaint as Exhibit B. Apotex denies the remaining allegations of this paragraph.

8. Apotex admits that U.S. Patent No. 11,192,895 (the "'895 patent"), issued on December 7, 2021, is entitled "Crystalline forms of 3-(imidazo[1,2-B] pyridazin-3-ylethynyl)-4-methyl-N-{4-[(4-methylpiperazin-1-yl) methyl]-3-(trifluoromethyl)phenyl} benzamide and its mono hydrochloride salt," with Christopher K. Murray, Leonard W. Rozamus, John J. Chaber, and Pradeep Sharma as the listed inventors on the face of the '895 patent. Apotex also admits that Ariad is listed as the assignee on the face of the '895 patent. Apotex further admits that what appears to be an uncertified copy of the '895 patent was attached to Takeda's Complaint as Exhibit C. Apotex denies the remaining allegations of this paragraph.

#### **RESPONSES AS TO THE ICLUSIG® DRUG PRODUCT**

9. Apotex lacks knowledge and information to form a belief as to the truth of the allegations of this paragraph, and avers that the New Drug Application ("NDA") No. 203469

speaks for itself with respect to its contents therein. To the extent this paragraph calls for a legal conclusion, no response is required. Apotex further avers that ponatinib hydrochloride tablets under approved NDA No. 203469 are marketed under the trade name ICLUSIG<sup>®</sup>, and that ICLUSIG<sup>®</sup> is an FDA-approved medication indicated for the treatment of certain forms of leukemia.

10. To the extent this paragraph calls for a legal conclusion, no response is required. Insofar as any response is required, Apotex lacks knowledge and information to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

11. Apotex admits that the '470 patent is listed in the Approved Drug Products with Therapeutic Equivalence Evaluations, with respect to ICLUSIG<sup>®</sup>. Apotex denies the remaining allegations of this paragraph.

12. Apotex lacks knowledge and information to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

13. Apotex lacks knowledge and information to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

14. Apotex lacks knowledge and information to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

#### **RESPONSES AS TO THE JURISDICTION AND VENUE**

15. This paragraph calls for a legal conclusion, and therefore no response is required. Insofar as any response is required, for the limited purpose of this action only, Apotex does not contest that this Court has subject matter jurisdiction over Takeda's claims.

16. Apotex lacks knowledge and information to form a belief as to the truth of the allegations of this paragraph, and therefore denies them. Apotex avers that Apotex is a

pharmaceutical company that produces high-quality affordable medicines (both generic and innovative pharmaceuticals) for patients around the world.

17. To the extent this paragraph calls for a legal conclusion, no response is required. For the limited purpose of this action only, Apotex does not contest personal jurisdiction in this judicial district. Apotex denies the remaining allegations of this paragraph.

18. To the extent this paragraph calls for a legal conclusion, no response is required. For the limited purpose of this action only, Apotex does not contest personal jurisdiction in this judicial district. Apotex denies the remaining allegations of this paragraph.

19. To the extent this paragraph calls for a legal conclusion, no response is required. For the limited purpose of this action only, Apotex does not contest personal jurisdiction in this judicial district. Apotex denies the remaining allegations of this paragraph.

20. To the extent this paragraph calls for a legal conclusion, no response is required. For the limited purpose of this action only, Apotex does not contest personal jurisdiction in this judicial district. Apotex denies the remaining allegations of this paragraph, and avers that it has previously been sued in, asserted counterclaims in suits brought in, and initiated litigation in this Judicial District.

21. To the extent this paragraph calls for a legal conclusion, no response is required. For the limited purpose of this action only, Apotex does not contest personal jurisdiction in this judicial district. Apotex admits it has previously been sued in this Judicial District and has asserted counterclaims in suits brought in New Jersey. Apotex denies the remaining allegations of this paragraph.

22. To the extent this paragraph calls for a legal conclusion, no response is required. For the limited purpose of this action only, Apotex does not contest personal jurisdiction in this

judicial district. Apotex admits it has initiated litigation in this Judicial District. Apotex denies the remaining allegations of this paragraph.

23. To the extent this paragraph calls for a legal conclusion, no response is required. For the limited purpose of this action only, Apotex does not contest personal jurisdiction in this judicial district. Apotex denies the remaining allegations of this paragraph.

24. To the extent this paragraph calls for a legal conclusion, no response is required. For the limited purpose of this action only, Apotex does not contest personal jurisdiction in this judicial district.

25. To the extent this paragraph calls for a legal conclusion, no response is required. For the limited purpose of this action only, Apotex does not contest venue in this judicial district. Apotex denies the remaining allegations of this paragraph.

#### **RESPONSES AS TO APOTEX'S ANDA SUBMISSION**

26. Apotex admits Apotex sent a letter dated May 14, 2021 ("Apotex Letter") stating that Apotex had submitted ANDA No. 215893 to the FDA to obtain approval to engage in the commercial manufacture, use, or sale of 15 mg and 45 mg ponatinib hydrochloride tablets before the expiration of the '470 patent.<sup>2</sup> Apotex denies the remaining allegations of this paragraph.

27. Apotex admits the allegations of this paragraph.

28. Apotex admits the allegations of this paragraph.

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<sup>2</sup> Plaintiffs' inclusion of a footnote does not comply with Federal Rule of Civil Procedure 10(b), requiring that allegations be stated "in numbered paragraphs, each limited as far as practicable to a single set of circumstances." As such, no response is required. Moreover, to the extent Plaintiffs' footnote calls for a legal conclusion, no response is required. To the extent a response is required, Apotex lacks knowledge and information to form a belief as to the truth of the allegations of this footnote, and therefore denies them.

29. Apotex lacks knowledge and information to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

30. To the extent this paragraph calls for a legal conclusion, no response is required. Insofar as any response is required, Apotex denies the allegations of this paragraph, and avers that its product is therapeutically equivalent to the Plaintiffs' ICLUSIG<sup>®</sup> product.

31. Apotex admits that the Apotex Letter alleges, *inter alia*, that the claims of the '470 patent are invalid and/or will not be infringed by the activities described in Apotex's ANDA. Apotex denies the remaining allegations of this paragraph.

32. To the extent this paragraph calls for a legal conclusion, no response is required. Apotex admits that the Court's Pretrial Scheduling Order (ECF No. 25) requires Plaintiffs to amend its complaint to add new patents and disclosure of asserted claims with respect to new patents 10 days after issuance of the patents. Insofar as any further response is required, Apotex lacks knowledge and information to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

**RESPONSES AS TO COUNT I**  
**As to the Alleged Infringement of U.S. Patent No. 9,493,470 by Apotex**

33. Apotex incorporates its responses to the preceding paragraphs as if fully set forth herein.

34. To the extent this paragraph calls for a legal conclusion, no response is required. Insofar as any response is required, Apotex denies the allegations of this paragraph.

35. To the extent this paragraph calls for a legal conclusion, no response is required. Insofar as any response is required, Apotex denies the allegations of this paragraph.

36. Apotex admits the allegations of this paragraph.

37. Apotex lacks knowledge and information to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

38. Apotex lacks knowledge and information to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

39. Apotex admits the allegations of this paragraph.

40. To the extent this paragraph calls for a legal conclusion, no response is required. Insofar as any response is required, Apotex lacks knowledge and information to form a belief as to the truth of the allegations of this paragraph.

41. To the extent this paragraph calls for a legal conclusion, no response is required. Insofar as any response is required, Apotex denies the allegations of this paragraph.

42. To the extent this paragraph calls for a legal conclusion, no response is required. Insofar as any response is required, Apotex denies the allegations of this paragraph.

43. To the extent this paragraph calls for a legal conclusion, no response is required. Insofar as any response is required, Apotex denies the allegations of this paragraph.

44. To the extent this paragraph calls for a legal conclusion, no response is required. Insofar as any response is required, Apotex lacks knowledge and information to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

45. To the extent this paragraph calls for a legal conclusion, no response is required. Insofar as any response is required, Apotex denies the allegations of this paragraph.

46. To the extent this paragraph calls for a legal conclusion, no response is required. Insofar as any response is required, Apotex denies the allegations of this paragraph.

**RESPONSES AS TO COUNT II**  
**As to the Alleged Infringement of U.S. Patent No. 11,192,897 by Apotex**



47. Apotex incorporates its responses to the preceding paragraphs as if fully set forth herein.

48. To the extent this paragraph calls for a legal conclusion, no response is required. Insofar as any response is required, Apotex denies the allegations of this paragraph.

49. To the extent this paragraph calls for a legal conclusion, no response is required. Insofar as any response is required, Apotex denies the allegations of this paragraph.

50. Apotex admits the allegations of this paragraph.

51. Apotex lacks knowledge and information to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

52. Apotex lacks knowledge and information to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

53. Apotex admits the allegations of this paragraph.

54. Apotex lacks knowledge and information to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

55. Apotex admits the allegations of this paragraph.

56. Apotex lacks knowledge and information to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

57. Apotex admits the allegations of this paragraph.

58. Apotex lacks knowledge and information to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

59. Apotex admits the allegations of this paragraph.

60. To the extent this paragraph calls for a legal conclusion, no response is required. Insofar as any response is required, Apotex lacks knowledge and information to form a belief as to the truth of the allegations of this paragraph.

61. Apotex admits the allegations of this paragraph.

62. To the extent this paragraph calls for a legal conclusion, no response is required. Insofar as any response is required, Apotex lacks knowledge and information to form a belief as to the truth of the allegations of this paragraph.

63. To the extent this paragraph calls for a legal conclusion, no response is required. Insofar as any response is required, Apotex denies the allegations of this paragraph.

64. To the extent this paragraph calls for a legal conclusion, no response is required. Insofar as any response is required, Apotex denies the allegations of this paragraph.

65. To the extent this paragraph calls for a legal conclusion, no response is required. Insofar as any response is required, Apotex denies the allegations of this paragraph.

66. To the extent this paragraph calls for a legal conclusion, no response is required. Insofar as any response is required, Apotex lacks knowledge and information to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

67. To the extent this paragraph calls for a legal conclusion, no response is required. Insofar as any response is required, Apotex denies the allegations of this paragraph.

68. To the extent this paragraph calls for a legal conclusion, no response is required. Insofar as any response is required, Apotex denies the allegations of this paragraph.

**RESPONSES AS TO COUNT III**  
**As to the Alleged Infringement of U.S. Patent No. 11,192,895 by Apotex**

69. Apotex incorporates its responses to the preceding paragraphs as if fully set forth herein.

70. To the extent this paragraph calls for a legal conclusion, no response is required.  
Insofar as any response is required, Apotex denies the allegations of this paragraph.

71. To the extent this paragraph calls for a legal conclusion, no response is required.  
Insofar as any response is required, Apotex denies the allegations of this paragraph.

72. Apotex admits the allegations of this paragraph.

73. To the extent this paragraph calls for a legal conclusion, no response is required.  
Insofar as any response is required, Apotex lacks knowledge and information to form a belief as to the truth of the allegations of this paragraph.

74. Apotex denies the allegations of this paragraph and avers that Claim 7 of the '895 patent recites:

A method for treating acute phase chronic myeloid leukemia in a subject in need thereof comprising administering to the subject a therapeutically effective amount of a pharmaceutical composition comprising at least one crystalline form of ponatinib hydrochloride characterized by:

- a) an x-ray powder diffraction pattern comprising at least three  $2\theta$  values ( $\pm 0.3$ ) chosen from 5.9, 7.1, 10.0, 12.5, 13.6, 14.1, 15.0, 16.4, 17.7, 18.6, 19.3, 20.4, 21.8, 22.3, 23.8, 24.9, 26.1, 27.0, 28.4, 30.3, 31.7, and 35.1;
- b) an x-ray powder diffraction pattern comprising at least three  $2\theta$  values ( $\pm 0.3$ ) chosen from 3.1, 6.5, 12.4, 13.8, 15.4, 16.2, 17.4, 18.0, 20.4, 23.2, 24.4, 26.1, and 26.9;
- c) an x-ray powder diffraction pattern comprising at least three  $2\theta$  values ( $\pm 0.3$ ) chosen from 3.1, 6.5, 12.4, 13.8, 17.4, 18.0, 20.6, 22.0, 23.0, 25.5, 26.5, 27.4, 28.4, and 29.0;
- d) an x-ray powder diffraction pattern comprising at least three  $2\theta$  values ( $\pm 0.3$ ) chosen from 8.2, 10.1, 10.9, 14.9, 16.0, 16.3, 16.8, 17.7, 18.7, 20.2, 22.9, 24.0, 25.6, 26.7, and 28.5
- e) an x-ray powder diffraction pattern substantially as shown in FIG. 41 labelled HCl1 + HCl4 (GRP1.1);
- f) an x-ray powder diffraction pattern comprising at least

three  $2\theta$  values ( $\pm 0.3$ ) chosen from 7.9, 8.7, 9.7, 11.4, 15.6, 16.5, and 25.8;

g) an x-ray powder diffraction pattern substantially as shown in FIG. 41 labelled HCl5b (VDS28.2);

h) an x-ray powder diffraction pattern comprising at least three  $2\theta$  values ( $\pm 0.3$ ) chosen from 8.0, 10.2, 10.9, 11.8, 14.1, 15.4, 16.3, 19.9, 22.3, 23.7, 25.0, and 28.2;

i) an x-ray powder diffraction pattern comprising at least three  $2\theta$  values ( $\pm 0.3$ ) chosen from 6.1, 7.0, 13.3, 16.4, 20.7, 22.2, 23.9, 25.5, and 29.1; or

j) an x-ray powder diffraction pattern comprising at least three  $2\theta$  values ( $\pm 0.3$ ) chosen from 6.1, 7.4, 13.5, 17.4, 18.5, 20.7, 23.9, and 28.3.

75. To the extent this paragraph calls for a legal conclusion, no response is required. Insofar as any response is required, Apotex lacks knowledge and information to form a belief as to the truth of the allegations of this paragraph.

76. Apotex admits the allegations of this paragraph.

77. To the extent this paragraph calls for a legal conclusion, no response is required. Insofar as any response is required, Apotex lacks knowledge and information to form a belief as to the truth of the allegations of this paragraph.

78. Apotex admits the allegations of this paragraph.

79. To the extent this paragraph calls for a legal conclusion, no response is required. Insofar as any response is required, Apotex lacks knowledge and information to form a belief as to the truth of the allegations of this paragraph.

80. To the extent this paragraph calls for a legal conclusion, no response is required. Insofar as any response is required, Apotex denies the allegations of this paragraph.

81. To the extent this paragraph calls for a legal conclusion, no response is required. Insofar as any response is required, Apotex denies the allegations of this paragraph.

82. To the extent this paragraph calls for a legal conclusion, no response is required. Insofar as any response is required, Apotex denies the allegations of this paragraph.

83. To the extent this paragraph calls for a legal conclusion, no response is required. Insofar as any response is required, Apotex lacks knowledge and information to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

84. To the extent this paragraph calls for a legal conclusion, no response is required. Insofar as any response is required, Apotex denies the allegations of this paragraph.

85. To the extent this paragraph calls for a legal conclusion, no response is required. Insofar as any response is required, Apotex denies the allegations of this paragraph.

#### **ANSWER TO TAKEDA'S PRAYER FOR RELIEF**

The remainder of Takeda's Complaint is a prayer for relief, and does not require a response. To the extent any response is required, Apotex denies that Takeda is entitled to any relief whatsoever against Apotex in this action, either as prayed for in the Complaint or otherwise.

#### **SEPARATE DEFENSES**

Apotex asserts the following defenses to the Complaint, without prejudice to the denials in this Answer, and without admitting any allegations of the Complaint not otherwise admitted. Apotex reserves the right to assert additional defenses, as warranted by facts learned through investigation and discovery. Assertion of a defense is not a concession that Apotex has the burden of proving the matter asserted.

#### **FIRST SEPARATE DEFENSE (Failure to State a Claim)**

Takeda's claims are barred in whole or in part because Takeda has not stated a claim upon which relief can be granted.

**SECOND SEPARATE DEFENSE**  
**(Invalidity of the '470 Patent)**

Upon information and belief, the claims of the '470 patent are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112 and general principles of patent law.

**THIRD SEPARATE DEFENSE**  
**(Non-Infringement of the '470 Patent)**

No acts by any entity related to Apotex have infringed, infringe, or will infringe any valid claim of the '470 patent.

**FOURTH SEPARATE DEFENSE**  
**(Invalidity of the '897 Patent)**

Upon information and belief, the claims of the '897 patent are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112 and general principles of patent law.

**FIFTH SEPARATE DEFENSE**  
**(Non-Infringement of the '897 Patent)**

No acts by any entity related to Apotex have infringed, infringe, or will infringe any valid claim of the '897 patent.

**SIXTH SEPARATE DEFENSE**  
**(Invalidity of the '895 Patent)**

Upon information and belief, the claims of the '895 patent are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112 and general principles of patent law.

**SEVENTH SEPARATE DEFENSE**  
**(Non-Infringement of the '895 Patent)**

No acts by any entity related to Apotex have infringed, infringe, or will infringe any valid claim of the '895 patent.

**EIGHTH SEPARATE DEFENSE**

Any additional defenses that discovery may reveal.

**PRAYER FOR RELIEF**

WHEREFORE, Apotex prays for relief as follows:

- A. That Takeda takes nothing by its claims for relief;
- B. That Takeda's Complaint be dismissed with prejudice and that Takeda's requests for relief be denied with prejudice;
- C. That the Court enter judgment against Takeda and in Apotex's favor in all respects;
- D. That the Court enter judgment that Claims 1-17 of the '470 patent are invalid;
- E. That the Court enter judgment that the manufacture, use, sale, offer for sale, or importation into the United States of the ANDA Products have not infringed, do not infringe, and would not, if marketed, infringe any valid and enforceable claim of the '470 patent;
- F. That the Court enter judgment that Claims 1-23 of the '897 patent are invalid;
- G. That the Court enter judgment that the manufacture, use, sale, offer for sale, or importation into the United States of the ANDA Products have not infringed, do not infringe, and would not, if marketed, infringe any valid and enforceable claim of the '897 patent;
- H. That the Court enter judgment that Claims 1-24 of the '895 patent are invalid;
- I. That the Court enter judgment that the manufacture, use, sale, offer for sale, or importation into the United States of the ANDA Products have not infringed, do not infringe, and would not, if marketed, infringe any valid and enforceable claim of the '895 patent;
- J. That the Court enter judgment that the FDA may approve ANDA No. 215893 concerning Apotex's ponatinib hydrochloride oral tablets, 15 mg and 45 mg, whenever that application is otherwise in condition for approval, without awaiting any further order, judgment, or decree of the Court; that the judgment entered in this case is a judgment reflecting a decision

that the Patents-in-Suit are invalid and/or not infringed pursuant to 21 U.S.C.

§ 355(j)(5)(B)(iii)(I)(aa); and that the thirty-month period referred to in 21 U.S.C.

§ 355(j)(5)(B)(iii) and any other marketing exclusivity periods to which Takeda might otherwise be entitled (including any pediatric exclusivity) are shortened to expire upon the date of entry of judgment in this case;

K. That the Court declare this case is exceptional under 35 U.S.C. § 285, and award Apotex its attorneys' fees and costs incurred in this action; and

L. For an award of such other and further relief as the Court may deem just and proper.

Respectfully submitted,

**SAIBER LLC**  
Attorneys for Defendant  
Apotex Inc.

Dated: December 27, 2021

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